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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,180	02/13/2002	Robert J. Hariri	009516-0050-999	9742

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NEW YORK, NY 100362711

EXAMINER

LI, QIAN J

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/076,180	HARIRI, ROBERT J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## **DETAILED ACTION**

### ***Claim Objections***

Claims 37, 39, 46-50 are objected to because they recite “the [placenta] stem [cell] of claim 35”, there is insufficient antecedent basis for the limitation in the claim. In view of the compact prosecution policy of the Office, these claims have been considered as depending from claim 36. Appropriate correction is required in response to this Office action.

Claims 42, 43, and 45 are objected to because they recite “the apparatus of claim 39”. There is insufficient antecedent basis for the limitation in the claim. In view of the compact prosecution policy, they have been considered as depending from claim 41. Appropriate correction is required in response to this Office action.

Claim 49 is objected to because they recite “the pharmaceutical composition of claim 46”. There is insufficient antecedent basis for the limitation in the claim. In view of the compact prosecution policy, it has been considered as depending from claim 48. Appropriate correction is required in response to this Office action.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-18, and 54 are drawn to an isolated mammalian placenta. Classified in class 435, and subclass 1.1.
- II. Claims 19-35 are drawn to a method of culturing a mammalian placenta. Classified in class 435, and subclass 2.

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- III. Claims 36-40, 46-49, 51-53, and 55-59 are drawn to a human placenta stem cell and a method of using such for treating diseases in humans. Classified in class 435, subclass 325.
- IV. Claims 41-45 are drawn to an apparatus for producing a stem cell. Classified in class 435, subclass 283.1.
- V. Claim 50 is drawn to a committed cell. Classified in class 435, and subclass 325.

2. The inventions are distinct, each from the other because of the following reasons.

The products of Inventions III, IV, and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination, a stem cell producing apparatus comprising a mammalian placenta, a means for culturing the placenta and a means for detecting stem cell, or a placenta comprising a stem cell, as claimed does not require the particulars of the subcombination as claimed because the other component(s) in each instance could lend patentability to the combination. The subcombination has separate utility, for example, the placenta could be used for producing bioactive molecules, and a stem cell could be used for generating differentiated cell populations or treating diseases.

Inventions III, V, and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the different inventions are drawn to different products, e.g. a differentiated mammalian placenta, a stem cell, and a committed cell, which have distinct biological structures and distinct functions, and they belong to different biological categories.

Inventions III, and II are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the different inventions are drawn to different processes, which are mutually exclusive methods for transplanting the stem cells *in vivo*, or organ culture *in vitro*. The different methods use different starting materials, have different method steps, and mode of operation, and require distinct technical considerations.

It is noted that currently defined invention groups III and V comprises multiple inventions. Claims of group III are drawn to an isolated human placenta stem cell, and the specification teaches, "the stem cells which may be obtained from the placenta include embryonic-like stem cells, multipotent cells, committed progenitor cells, and fibroblastoid cells" (Specification, page 20, lines 25-26). Apparently, the currently defined group III encompasses more than one invention, drawn to different type of stem cells, which have different structure and function, and require different search criteria. Likewise, the committed cells derived from the differentiation of distinct stem cells (group V) would be distinct in the biological structure and function, and require different search criteria. If one of the invention groups III and V is elected, further election of an invention drawn to a particular cell type is necessary, e.g. a multipotent stem cell, a hematopoietic stem cell, a type of progenitor cell, and a fibroblast stem cells, etc.

Please note that this would be an election of an invention, not a species. The election should also be accompanied by a list of claims that read on the elected invention.

The differences of the Inventions I-V are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

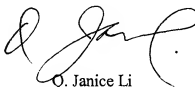
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Clark can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
April 15, 2003